PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 20 April 2001 (20.04.01)	
International application No. PCT/IB00/01149	**Applicant's or agent's file reference** P428525 BMP
International filing date (day/month/year) 23 August 2000 (23.08.00)	**Priority date** (day/month/year) 23 August 1999 (23.08.99)
Applicant CLARK, Simon, Peter	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

15 March 2001 (15.03.01)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer S. Mafla
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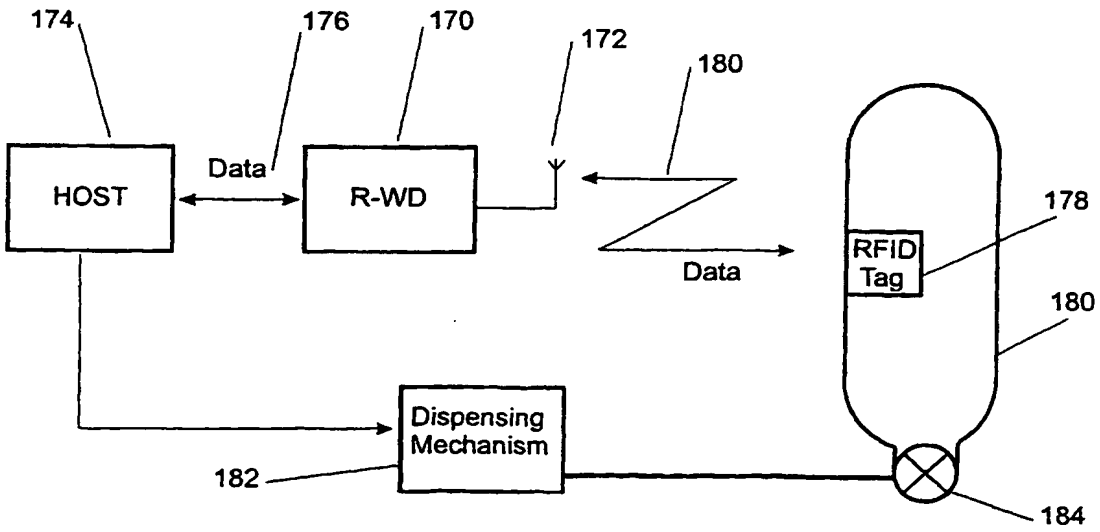
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: A DEVICE FOR INHIBITING USE OF NON-PROPRIETARY CONSUMABLES



(57) Abstract: An apparatus for preventing the use of unauthorised disposable or consumable components (180) and allowing use of authorised disposable or consumable components (180) in conjunction with scientific apparatus (170, 174) where each authorised disposable or consumables has an associated transponder (178). If the apparatus does not sense an authorised transponder it will prevent its operation.

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"A DEVICE FOR INHIBITING USE OF NON-PROPRIETARY CONSUMABLES"

TECHNICAL FIELD

This invention relates to the use of an article identifier, particularly though not solely, for inhibiting the use of non proprietary consumables.

BACKGROUND ART

In the scientific field there are a number of applications where manufacturers initially sell scientific equipment on the basis that they will subsequently continue to sell consumables in relation to and for use with that equipment. However there are a number of instances where other parties have subsequently entered the market and produced a variant on the proprietary consumables. This raises a number of issues for which it may be desirable that the proprietor be able to inhibit the use of any such unauthorised consumables.

Generally, the proprietor has no control over the quality of any of the consumables sold by its competitors. Thus in particularly critical applications such as medical equipment or chemical analysers where quality assurance of the entire system is critical, the use of non proprietary consumables may reduce the level of confidence in quality, and possibly even safety, of the equipment used. Therefore from the proprietor's perspective it would be desirable that the integrity of the equipment is preserved and to this end that the use of non proprietary consumables be inhibited.

DISCLOSURE OF THE INVENTION

It is an object of the present invention to provide an article identifier which goes some way towards meeting the above-mentioned desideratum or which will at least provide the public with a useful choice.

In a first aspect the present invention may be broadly said to consist in an apparatus for preventing use of unauthorised disposable or consumable components and allowing use of authorised disposable or consumable components in conjunction with scientific apparatus comprising:

identification means associated with said authorised disposable or consumables,

sensing means associated with said scientific apparatus, and

control means which inhibits the operation of said scientific apparatus unless said sensing means detects said identification means.

Preferably said control means includes a processor programmed with a stored program and either said identification means or said control means includes one or more registers, said program when executed on said processor causes said control means to carry out the steps of:

1) establishing communication between said control means and said identification means and if this is not successfully completed, halting the program and returning a negative result;

2) interrogating one or more registers in said identification means or said control means and using the information contained therein to predict whether the component said identification means is associated with, is in an acceptable state for use with said scientific apparatus and if not, halting the program and returning a negative result;

3) halting the program and returning a positive result.

Preferably said program is executed every time said scientific apparatus is operated and wherein said control means will inhibit the operation of said scientific apparatus unless a positive result is returned from said program.

Preferably said identifier means comprises an interrogatable radio frequency identification device.

Preferably said scientific apparatus comprises a chemical analyser and said disposable or consumable components comprise at least one reagent.

Alternatively said medical or analytical apparatus comprises a medical laser system and said disposable components comprise optical fibres.

In a further alternative said scientific apparatus comprise intra vascular diagnostic equipment adapted for internal diagnosis and treatment of a patient, and said disposable or consumable components comprise catheter means which in use conveys a portion of said vascular diagnostic equipment into the vascular cavity of said patient.

In a further alternative said scientific apparatus comprise tissue processing equipment including slide means adapted to support said tissue in use and said disposable or consumable components comprise fixative fluids or solvents which in use fix the said tissue to said slide.

In a further alternative said scientific apparatus comprise tissue analysing equipment including slide means adapted to support said tissue in use and said disposable or consumable components comprise slide staining means which are adapted to in use stain the said tissue.

In a further alternative said scientific apparatus comprise haemodialysing equipment adapted to filter the blood of a patient and said disposable or consumable components comprise a dialysis unit including a filter which in use removes waste products from said patient's blood which is circulated by said haemodialysing equipment.

In a second aspect the present invention may be broadly said to consist in a chemical analyser comprising:

a reagent dispenser including a reagent vial,

identification means associated with said reagent vial,

sensing means associated with said chemical analyser, and

control means which inhibits the operation of said chemical analyser unless said sensing means detects said identification means.

In a third aspect the present invention may be broadly said to consist in a medical laser system for treating a patient comprising:

laser generating means,

optical means for conveying said laser from said laser generating means to said patient,

identification means associated with said optical means,

sensing means associated with said medical laser system,

control means which inhibits the operation of said medical laser system unless said sensing means detects said identification means.

In a fourth aspect, the present invention may be broadly said to consist in an apparatus for preventing use of unauthorised disposable or consumable components and allowing use of authorised disposable or consumable components in conjunction with scientific apparatus comprising:

identification means associated with said authorised disposable or consumables,

sensing means associated with said scientific apparatus, and

control means programmed with stored instructions comprising the steps of:

1) establishing communication between said control means and said identification means and if this is not successfully completed, inhibiting the operation at said scientific apparatus and halting.

2) predict whether the component said identification means is associated with, is in an acceptable state for use with said scientific apparatus based on information stored in either said identification means or said control means and if not, inhibiting the operation of said scientific equipment and halting.

3) permitting the operation of said scientific equipment.

Preferably said identifier means comprises an interrogatable radio frequency identification device.

Preferably said scientific apparatus comprises a chemical analyser and said disposable or consumable components comprise at least one reagent.

Alternatively said medical or analytical apparatus comprises a medical laser system and said disposable components comprise optical fibres.

In a further alternative said scientific apparatus comprise intra vascular diagnostic equipment adapted for internal diagnosis and treatment of a patient, and said disposable or consumable components comprise catheter means which in use conveys a portion of said vascular diagnostic equipment into the vascular cavity of said patient.

In a further alternative said scientific apparatus comprise tissue processing equipment including slide means adapted to support said tissue in use and said disposable or consumable components comprise fixative fluids or solvents which in use fix the said tissue to said slide.

In a further alternative said scientific apparatus comprise tissue analysing equipment including slide means adapted to support said tissue in use and said disposable or consumable components comprise slide staining means which are adapted to in use stain the said tissue.

In a further alternative said scientific apparatus comprise haemodialysing equipment adapted to filter the blood of a patient and said disposable or consumable components comprise a dialysis unit including a filter which in use removes waste products from said patient's blood which is circulated by said haemodialysing equipment.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF DRAWINGS

One preferred form of the present invention will now be described with reference to the accompanying drawings in which;

Figure 1 is a block diagram of the present invention according to the first preferred embodiment,

Figure 2 is a flow diagram of the control strategy according to the present invention,

Figure 3 is a block diagram of the electronic apparatus according to the present invention, and

Figure 4 is a block diagram of the present invention according to the second preferred embodiment.

MODES FOR CARRYING OUT THE INVENTION

The present invention provides a means for controlling the use of consumable or disposable components for use with scientific equipment. In the preferred embodiment the present invention will prohibit operation of the scientific equipment where the consumable or disposable components are not authorised and therefore do not include an electronic identifier. This system has flexibility in that where such components may be used several times before being discarded, the electronic identifier

can keep track of how many times each component has been used and when depleted it will bar operation of the device until the component in question is replaced with a new authorised component.

One application where the present invention is of particular advantage is chemical analysers which use a consumable chemical reagent each time particular substance is tested for the presence or absence of a particular chemical. A chemical analyser such as would be appropriate for use with the present invention is shown in Figure 1 . It is seen that the analyser 110 comprises a number of generic components including the reagent dispenser 112, a carousel 114, test vessels 116 and a testing and analysis stage 118. The reagent dispenser 112 includes a removable vial 120 which is filled with bulk reagent 122.

In the preferred embodiment of the present invention the vial 120 includes an electronic identifier 124 integrated into the neck 126. It will be appreciated however that the electronic identifier 124 could be located anywhere in association with the vial 112 and in fact could be of the form of a smart card type device independent of the vial which is recharged when the reagent vial is refilled from a authorised stockist.

Control Methodology

Whatever the application, the interrogation of the identifier to complete the authorisation process will follow an essentially generic path. Figure 2 illustrates this process in the form of a flow diagram. Whenever the apparatus in question starts up the authorisation algorithm runs through and if successful then the operation of the apparatus proceeds.

The first step is the application of the RF field 150 to initiate communications with the identifier. It will be appreciated that the content of this first step is dependent on the method of identification that is used. The RF field is applied for a set period 152 waiting for a response from the identifier. If one is not received within this period, the algorithm halts 154 with a negative result. If communication is established, the first register in the identifier is interrogated 156. This contains a date value relating to the device's "use by" date. If the "use by" date has passed, the device is deemed expired, and the algorithm halts 158 with a negative result. If not, the second register is

interrogated 160, which contains information on the remaining use allowed for the device. If no use remains the device is deemed depleted and the algorithm halts 162 with a negative result. If there is remaining use, the use counter is decremented by one or more units 164, and the algorithm halts with a positive result 166.

It will be appreciated that the operation of the apparatus is conditional on the return of a positive result from the authorisation algorithm. Further where there is a negative result specific error codes could be returned allowing messages to be displayed to the user informing them of the problem and possible solutions.

Component Identifier

In the preferred embodiment of the present invention the identifier is in the form of a electronic radio frequency identification (RFID) interrogatable device. RFIDs use wireless communication to transmit and receive data from a transceiver to a transponder and where the transponder itself may only be readable or read writable where instructions are to be passed in both directions. Referring now to Figure 3 the transceiver 170, including an antenna 172 or a coil, is a preferred embodiment of the present invention integrated with the chemical analyser in closer proximity to where the reagent vial is situated. The transceiver 170 is controlled by either a separate microcontroller 174 specifically for the authorisation process or where the analyser has its own micro controller it can be controlled by that. However the transceiver is controlled, there will still need to be some form of data link 176 to allow the overall operation of the analyser to be inhibited if the authorisation process is not correctly completed.

The transponder 178 or RF tag as they are sometimes known will be located somewhere on the reagent vial 180 as already described. There are a number of methods of transferring information from the transponder to the transceiver. In the preferred embodiment for the present invention, radio frequency propagation 180 in the range 10-15 MHZ is used for communication between the transceiver and transponder. This provides access to well-proven technology on a mass produced scale and a good data transfer rate. It will be appreciated that while one method is described for the preferred embodiment of the present invention, many other methods will be equally

possible eg: infrared or laser signalling, inductive coupling, capacitative coupling, electrostatic methods, direct electrical connection and, for that matter, a simple device such as barcode and scanner could be utilised in variations on the present invention.

The previously described algorithm is executed on the apparatus controller 174, which in turn controls the dispensing mechanism which may in turn activate a valve 184 to control the reagent dispensation.

The transponder itself may be embodied in any one of a number of forms. It may simply include an authentication code to ensure it has been sourced from an authorised source or may also include one or more registers which store any manner of information in relation to the apparatus. As indicated in the foregoing description, information on the use-by date of the current stock of reagents might be stored in order to ensure that once it has passed this expiry date it is prevented from being used. Further, such registers may be used to store the amount of reagent used to date and therefore to indicate how much reagent remains and therefore when the file is empty.

Further Applications

As already mentioned the present invention is applicable to scientific equipment in general. Another application in which such a device would be particularly useful is with disposable medical articles. One example is fibre optic strands used with a surgical laser system, where the fibres are inserted internally into the body. It will be appreciated however that many similar applications exist and this application is only given by way of example.

Referring now to Figure 4, a surgical laser system is illustrated which is adapted for use with the present invention. The laser beam itself is initiated in the generator module 200 which is controlled by the control and display module 202. The laser beam is channelled through a fibre optic strand 204 which is protected with an outer semi-rigid sheath. The internal positioning of the strand 204 within a patent 206 is controlled by a hand held controller 208 which adjusts both lateral and proximity positioning of the open end of the strand 204.

The strand 204 itself, as it is exposed to bodily fluids, must either be disposed of and replaced after every use, or thoroughly disinfected. Quality and safety demands necessitate that disposal is the preferred alternative.

As previously mentioned, it is preferable that where disposable components are to be used they be of dependable levels of quality and safety. To this end, the present invention provides a means of ensuring only components from authorised sources can be used with the surgical laser system.

As with applications in the chemical analyser previously described, an identifier is associated with each disposable component. In practice, an identifier is integrated into the connector 210 at the point where the strand is attached to the generator module 200.

Using the method previously described, the operation of the laser is conditional on the correct authorisation process being completed between an interrogator integrated in the generator module 200 and the identifier associated with the strand 204.

Another application might be where heart disease is investigated and treated with catheters that are inserted into the vascular system and directed into the heart. In many cases the catheters carry electrical conductors that allow the electrical events associated with cardiac contraction to be observed and recorded by equipment (for example an electrocardiograph). In some cases the catheters carry conductors or radio frequency wave-guides that allow electromagnetic energy to be conveyed to the heart for treatment purposes. The present invention might be incorporated within the electrocardiograph or within a source of rf energy in order to inhibit the reuse of disposable catheters.

In the case of processing of tissue specimens in automated processors, a variety of fixative fluids and solvents are employed so that they can subsequently be transformed into microscopic slides. The present invention might be incorporated within the processor and the various fluid containers to control the use of non-proprietary solvents.

In a similar vein a variety of biological specimens, including tissue, blood, and other body fluids are applied to a glass substrate ("slide") and examined microscopically after the specimens have been stained. Various devices exist to stain the slides. In one application of the present invention the device could be incorporated within the automated stainer and the containers that store the stains to control the use of non-proprietary stains or reagents.

Patients with renal disease may be treated with extra-corporeal haemodialysis. Haemodialysers pump blood from the patient through a dialysis unit that removes waste products from the blood, after which the blood is returned to the patient. The dialysis units are frequently designed to be disposable, but in some cases have been cleaned and reused, with subsequent injury to the patients. The present invention could be incorporated within the haemodialyser to inhibit reuse.

CLAIMS:

1. An apparatus for preventing use of unauthorised disposable or consumable components and allowing use of authorised disposable or consumable components in conjunction with scientific apparatus comprising:

identification means associated with said authorised disposable or consumables,

sensing means associated with said scientific apparatus, and

control means which inhibits the operation of said scientific apparatus unless said sensing means detects said identification means.

2. An apparatus as claimed in claim 1 wherein said control means includes a processor programmed with a stored program and either said identification means or said control means includes one or more registers, said program when executed on said processor causes said control means to carry out the steps of:

1) establishing communication between said control means and said identification means and if this is not successfully completed, halting the program and returning a negative result;

2) interrogating one or more registers in said identification means or said control means and using the information contained therein to predict whether the component said identification means is associated with, is in an acceptable state for use with said scientific apparatus and if not, halting the program and returning a negative result;

3) halting the program and returning a positive result.

3. An apparatus as claimed in claim 2 wherein said program is executed every time said scientific apparatus is operated and wherein said control means will inhibit the operation of said scientific apparatus unless a positive result is returned from said program.

4. An apparatus as claimed in any one of claims 1 to 3 wherein said identifier means comprises an interrogatable radio frequency identification device.

5. An apparatus as claimed in any one of claims 1 to 4 wherein said scientific apparatus comprises a chemical analyser and said disposable or consumable components comprise at least one reagent.

6. An apparatus as claimed in any one of claims 1 to 4 wherein said medical or analytical apparatus comprises a medical laser system and said disposable components comprise optical fibres.

7. An apparatus as claimed in any one of claims 1 to 4 wherein said scientific apparatus comprise intra vascular diagnostic equipment adapted for internal diagnosis and treatment of a patient, and said disposable or consumable components comprise catheter means which in use conveys a portion of said vascular diagnostic equipment into the vascular cavity of said patient.

8. An apparatus as claimed in any one of claims 1 to 4 wherein said scientific apparatus comprise tissue processing equipment including slide means adapted to support said tissue in use and said disposable or consumable components comprise fixative fluids or solvents which in use fix the said tissue to said slide.

9. An apparatus as claimed in any one of claims 1 to 4 wherein said scientific apparatus comprise tissue analysing equipment including slide means adapted to support said tissue in use and said disposable or consumable components comprise slide staining means which are adapted to in use stain the said tissue.

10. An apparatus as claimed in any one of claims 1 to 4 wherein said scientific apparatus comprise haemodialysing equipment adapted to filter the blood of a patient

and said disposable or consumable components comprise a dialysis unit including a filter which in use removes waste products from said patient's blood which is circulated by said haemodialysing equipment.

11. A chemical analyser comprising:

a reagent dispenser including a reagent vial,

identification means associated with said reagent vial,

sensing means associated with said chemical analyser, and

control means which inhibits the operation of said chemical analyser unless said sensing means detects said identification means.

12. A medical laser system for treating a patient comprising:

laser generating means,

optical means for conveying said laser from said laser generating means to said patient,

identification means associated with said optical means,

sensing means associated with said medical laser system,

control means which inhibits the operation of said medical laser system unless said sensing means detects said identification means.

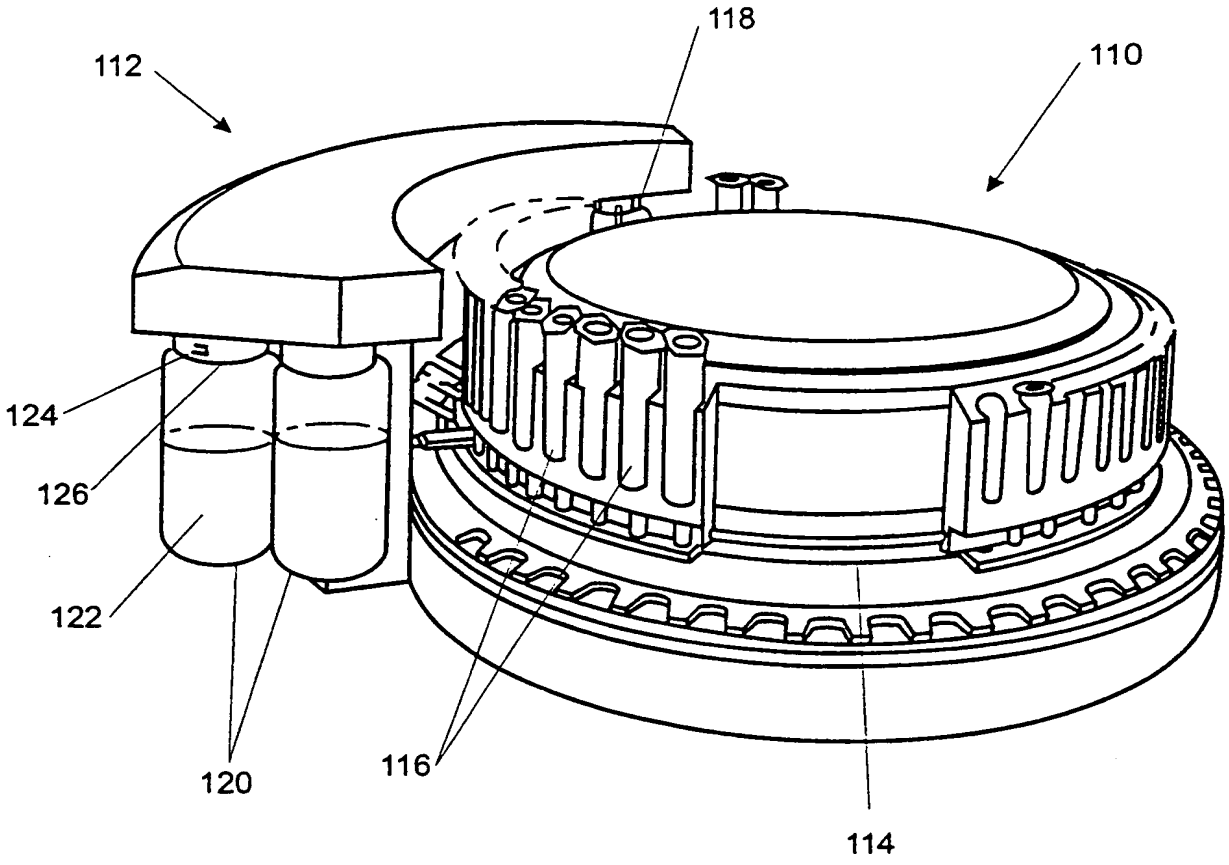
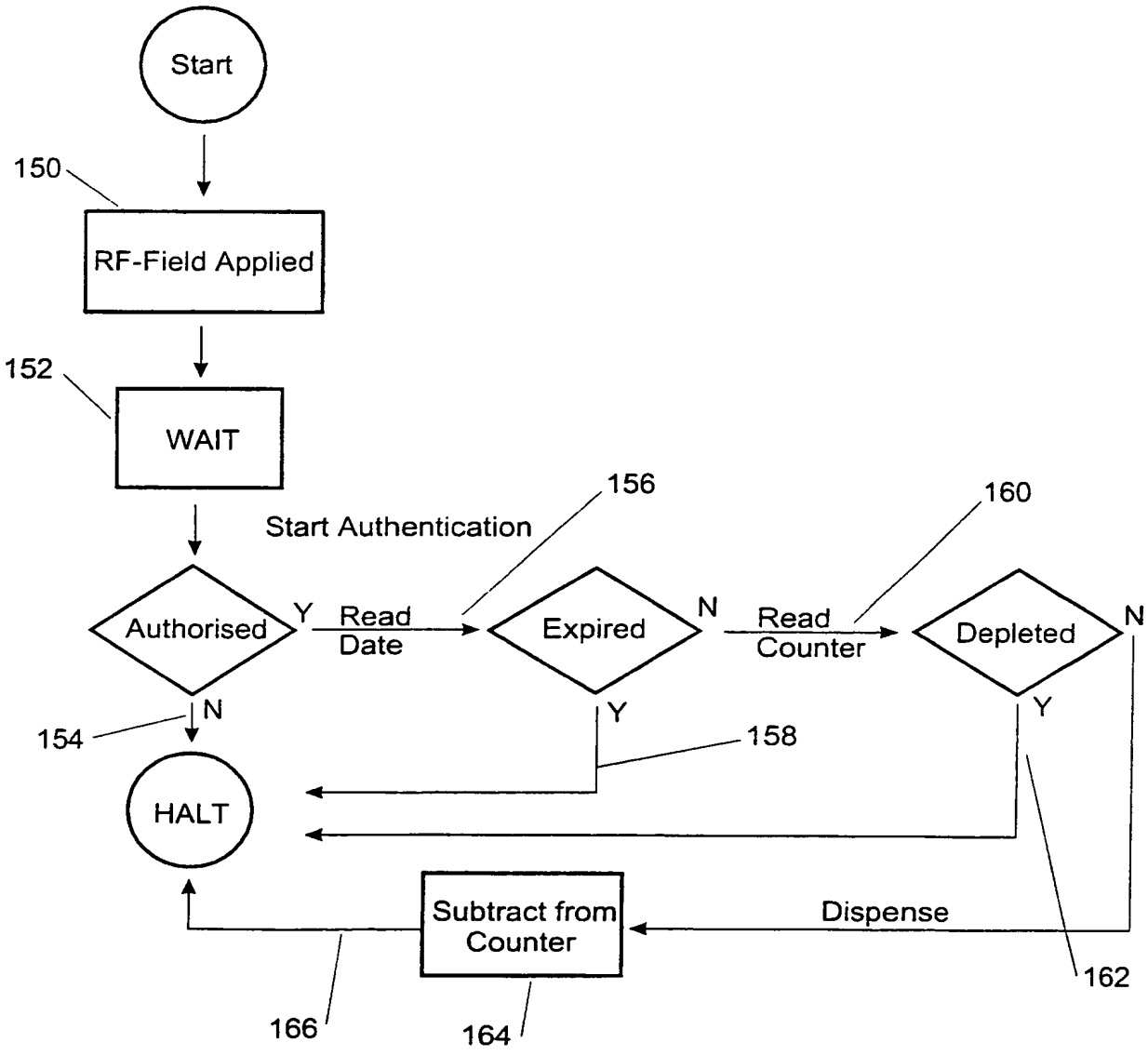


FIGURE 1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156
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Y
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N
154
158
HALT
Subtract from Counter
Dispense
162
166
164

FIGURE 2

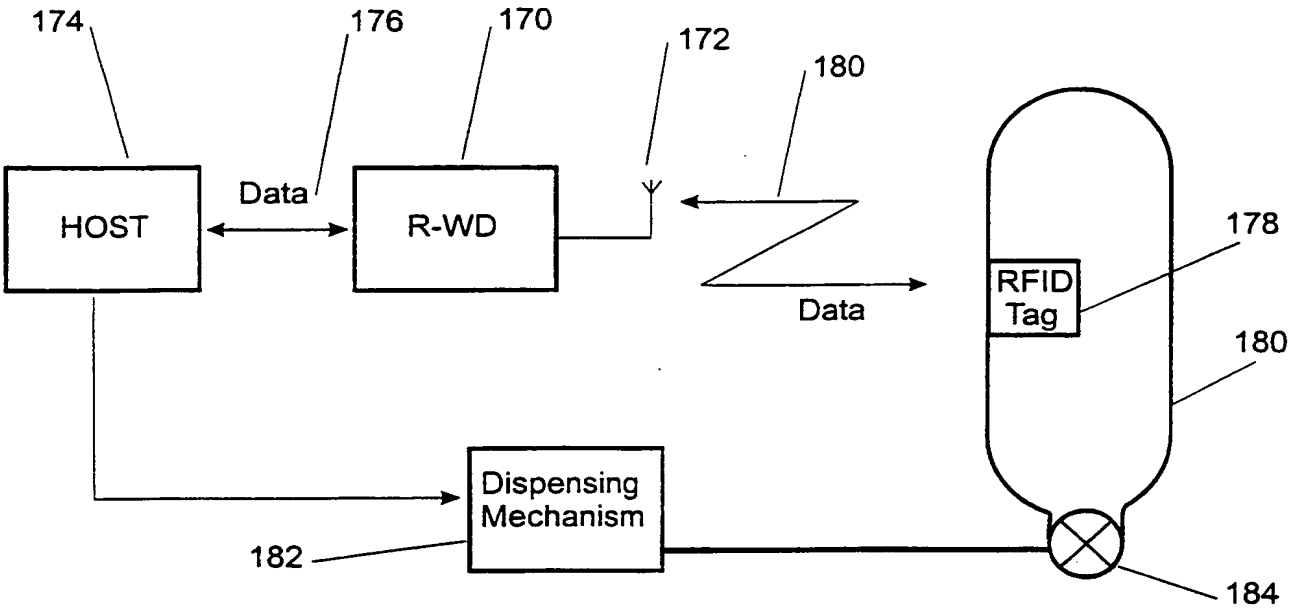

FIGURE 3

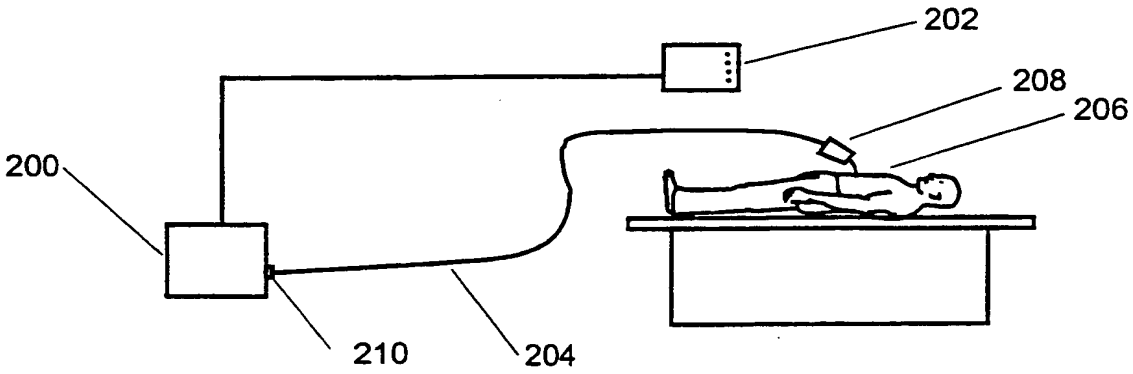

FIGURE 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB 00/01149

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[7]: G01V 15/00, G06K 7/00, G08B 29/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC G01V 15/00, G06K 7/IC, 9/IC, 11/IC, 19/IC, G07B 11/00, G08B 29/IC, G09F 9/IC

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU : IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI and JAPIO

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5652803 A (TACHIKAWA et al) 29 July 1997 col 2, lines 10-44	1-3
X	US 5647010 A (OKUBO et al) 8 July 1997 Abstract, col 2, lines 1-14, col 17, lines 25-53	1-3
X	US 5216724 A (SUSUKI et al) 1 June 1993 col2, lines 25-33, col 4, lines 42-61; col 12, lines 38-53	1-3

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

"A" Document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
03 November 2000	10 NOV 2000

Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No.: (02) 6285 3929	M.E. DIXON Telephone No.: (02) 6283 2194

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB 00/01149

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 91/10971 A (UTVECKLINGS AB JONIC) 25 July 1991 page 2, line 27 - page 3, line 11	1
A	WO 94/08867 A (HARTEK S.A.) 28 April 1994	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IB 00/01149

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member		
US	5652803	GB 2275387	JP 6062238	US 5659628
		WO 9403998	JP 6060165	
US	5647010	DE 4432741	JP 7087309	JP 7273984
		CA 2009699	EP 382549	EP 665477
		JP 2210481	US 5426710	US 5621810
		US 6128401	JP 2210591.	JP 2284189
		JP 2288488		
WO	91/10971	AU 51049/90	BR 9007977	EP 511204
		NO 922780	US 5350907	CA 2073449
		EP 890930		
WO	94/08867	EP 617685	FR 2696999	

END OF ANNEX

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P428525BMP/tma	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. **PCT/IB 00/01149**	International filing date *(day/month/year)* 23 August 2000	Priority Date *(day/month/year)* 23 August 1999

International Patent Classification (IPC) or national classification and IPC

Int. Cl.[7] G01V 15/00,G06K 7/00, G08B 29/00.

Applicant

1. CLARK, Simon Peter

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of **5** sheets, including this cover sheet.

[X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of **3** sheet(s).

3. This report contains indications relating to the following items:

I	[X]	Basis of the report
II	[ ]	Priority
III	[X]	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	[ ]	Lack of unity of invention
V	[X]	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	[ ]	Certain documents cited
VII	[X]	Certain defects in the international application
VIII	[ ]	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
15 March 2001	02 July 2001
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer M.E. DIXON Telephone No. (02) 6283 2194

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed.

☒ the description, pages **1-10, 14,** as originally filed,
pages , filed with the demand,
pages , received on with the letter of .

☒ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages **11-13,** received on **20 June 2001** with the letter of **19 June 2001.**

☒ the drawings, pages **1-3,** as originally filed,
pages , filed with the demand,
pages , received on with the letter of .

☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of .

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/fig

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be nonobvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos.: **13-15**

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claim Nos. **13-15**

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims **1-12**	**YES**
	Claims	**NO**
Inventive step (IS)	Claims **1-12**	**YES**
	Claims	**NO**
Industrial applicability (IA)	Claims **1-12**	**YES**
	Claims	**NO**

2. Citations and explanations (Rule 70.7)

NOVELTY (N) and INVENTIVE STEP (IS) claims 1-12

(1) US 5652803
(2) US 5647010
(3) US 5216724
(4) WO 91/10971

Amended claim 1 is a combination of original claims 1, 2. The amended claim defines an apparatus for preventing the use of unauthorised disposable or consumable components and for allowing the use of authorised consumable or disposable components in conjunction with scientific apparatus comprising the features of original claim 1:
identification means associated with the authorised disposable or consumable component,
sensing means associated with the scientific apparatus,
control means which prevent the operation of scientific apparatus unless the sensor can detect the identification means.

The control means is further limited in amended claim 1 by the addition of features in original claim 2. More importantly, it includes a feature defined in original claim 2, paragraph (2), that requires the control means to investigate the identification means or control means to predict whether the component the identification means is associated with, is in an acceptable state for use with the scientific apparatus.

The last named feature is not disclosed in any of the citations listed.

Independent claims 11, 12 are similar to original claim 1 except that these claims are directed to a particular application of the apparatus of original claim 1. Claim 11 is directed to a chemical analyser and claim 12 is directed to a medical laser system.

The features of claims 1, 11, 12 are not disclosed in any of the citations listed. Hence, claims 1-12 are novel and possess an inventive step over and above the disclosure in the the prior art.

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claims 13-15 rely on references to descriptions and drawings (Rule 6.2(a))

CLAIMS:

1. An apparatus for preventing use of unauthorised disposable or consumable components and allowing use of authorised disposable or consumable components in conjunction with scientific apparatus comprising:

identification means associated with said authorised disposable or consumables,

sensing means associated with said scientific apparatus, and

control means which inhibits the operation of said scientific apparatus unless said sensing means detects said identification means.

2. An apparatus as claimed in claim 1 wherein said control means includes a processor programmed with a stored program and either said identification means or said control means includes one or more registers, said program when executed on said processor causes said control means to carry out the steps of:

1) establishing communication between said control means and said identification means and if this is not successfully completed, halting the program and returning a negative result;

2) interrogating one or more registers in said identification means or said control means and using the information contained therein to predict whether the component said identification means is associated with, is in an acceptable state for use with said scientific apparatus and if not, halting the program and returning a negative result;

3) halting the program and returning a positive result.

3. An apparatus as claimed in claim 2 wherein said program is executed every time said scientific apparatus is operated and wherein said control means will inhibit the operation of said scientific apparatus unless a positive result is returned from said program.

4. An apparatus as claimed in any one of claims 1 to 3 wherein said identifier means comprises an interrogatable radio frequency identification device.

5. An apparatus as claimed in any one of claims 1 to 4 wherein said scientific apparatus comprises a chemical analyser and said disposable or consumable components comprise at least one reagent.

6. An apparatus as claimed in any one of claims 1 to 4 wherein said medical or analytical apparatus comprises a medical laser system and said disposable components comprise optical fibres.

7. An apparatus as claimed in any one of claims 1 to 4 wherein said scientific apparatus comprise intra vascular diagnostic equipment adapted for internal diagnosis and treatment of a patient, and said disposable or consumable components comprise catheter means which in use conveys a portion of said vascular diagnostic equipment into the vascular cavity of said patient.

8. An apparatus as claimed in any one of claims 1 to 4 wherein said scientific apparatus comprise tissue processing equipment including slide means adapted to support said tissue in use and said disposable or consumable components comprise fixative fluids or solvents which in use fix the said tissue to said slide.

9. An apparatus as claimed in any one of claims 1 to 4 wherein said scientific apparatus comprise tissue analysing equipment including slide means adapted to support said tissue in use and said disposable or consumable components comprise slide staining means which are adapted to in use stain the said tissue.

10. An apparatus as claimed in any one of claims 1 to 4 wherein said scientific apparatus comprise haemodialysing equipment adapted to filter the blood of a patient

and said disposable r consumabl components comprise a dialysis unit including a filter which in use removes waste products from said patient's blood which is circulated by said haemodialysing equipment.

11. A chemical analyser comprising:

a reagent dispenser including a reagent vial,

identification means associated with said reagent vial,

sensing means associated with said chemical analyser, and

control means which inhibits the operation of said chemical analyser unless said sensing means detects said identification means.

12. A medical laser system for treating a patient comprising:

laser generating means,

optical means for conveying said laser from said laser generating means to said patient,

identification means associated with said optical means,

sensing means associated with said medical laser system,

control means which inhibits the operation of said medical laser system unless said sensing means detects said identification means.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P428525BMP/tma	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. **PCT/IB 00/01149**	International filing date *(day/month/year)* 23 August 2000	Priority Date *(day/month/year)* 23 August 1999
International Patent Classification (IPC) or national classification and IPC **Int. Cl.**[7] G01V 15/00,G06K 7/00, G08B 29/00.		
Applicant 1. CLARK, Simon Peter		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheet(s).

3. This report contains indications relating to the following items:

I	[X]	Basis of the report
II	[ ]	Priority
III	[X]	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	[ ]	Lack of unity of invention
V	[X]	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	[ ]	Certain documents cited
VII	[X]	Certain defects in the international application
VIII	[ ]	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
15 March 2001	02 July 2001
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA E-mail address: pct@ipaustralia.g v.au Facsimile No. (02) 6285 3929	Authorized Officer M.E. DIXON Telephone N . (02) 6283 2194

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/IB 00/01149

I. Basis of the report

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☒ claims Nos.: **13-15**

because:

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step r industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-12	YES
	Claims	NO
Inventive step (IS)	Claims 1-12	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-12	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

NOVELTY (N) and INVENTIVE STEP (IS) claims 1-12

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Amended claim 1 is a combination of original claims 1, 2. The amended claim defines an apparatus for preventing the use of unauthorised disposable or consumable components and for allowing the use of authorised consumable or disposable components in conjunction with scientific apparatus comprising the features of original claim 1:
identification means associated with the authorised disposable or consumable component,
sensing means associated with the scientific apparatus,
control means which prevent the operation of scientific apparatus unless the sensor can detect the identification means.

The control means is further limited in amended claim 1 by the addition of features in original claim 2. More importantly, it includes a feature defined in original claim 2, paragraph (2), that requires the control means to investigate the identification means or control means to predict whether the component the identification means is associated with, is in an acceptable state for use with the scientific apparatus.

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CLAIMS:

1. An apparatus for preventing use of unauthorised disposable or consumable components and allowing use of authorised disposable or consumable components in conjunction with scientific apparatus comprising:

identification means associated with said authorised disposable or consumables,

sensing means associated with said scientific apparatus, and

control means which inhibits the operation of said scientific apparatus unless said sensing means detects said identification means, said control means including storage means programmed with a stored program, and either said identification means or said control means includes one or more registers, said program when executed causes said control means to carry out the steps of:

1) establishing communication between said control means and said identification means and if this is not successfully completed, halting the program and returning a negative result;

2) interrogating one or more registers in said identification means or said control means and using the information contained therein to determine whether the component said identification means is associated with, is in an acceptable state for use with said scientific apparatus and if not, halting the program and returning a negative result;

3) otherwise halting the program and returning a positive result.

2. An apparatus as claimed in claim 2 wherein said program is executed every time said scientific apparatus is operated and wherein said control means will inhibit the operation of said scientific apparatus unless a positive result is returned from said program.

3. An apparatus as claimed in claims 1 or 2 wherein one or more said registers at least store information on the number or length of usage f said component.

4. An apparatus as claimed in any one of claims 1 to 3 wherein said identifier means comprises an interrogatable radio frequency identification device.

5. An apparatus as claimed in any one of claims 1 to 4 wherein said scientific apparatus comprises a chemical analyser and said disposable or consumable components comprise at least one reagent.

6. An apparatus as claimed in any one of claims 1 to 4 wherein said scientific apparatus comprises a medical laser system and said disposable components comprise optical fibres.

7. An apparatus as claimed in any one of claims 1 to 4 wherein said scientific apparatus comprise intra vascular diagnostic equipment adapted for internal diagnosis and treatment of a patient, and said disposable or consumable components comprise catheter means which in use conveys a portion of said vascular diagnostic equipment into the vascular cavity of said patient.

8. An apparatus as claimed in any one of claims 1 to 4 wherein said scientific apparatus comprise tissue processing equipment including slide means adapted to support said tissue in use and said disposable or consumable components comprise fixative fluids or solvents which in use fix the said tissue to said slide.

9. An apparatus as claimed in any one of claims 1 to 4 wherein said scientific apparatus comprise tissue analysing equipment including slide means adapted to support said tissue in use and said disposable or consumable components comprise slide staining means which are adapted to in use stain the said tissue.

10. An apparatus as claimed in any one of claims 1 to 4 wherein said scientific apparatus comprise haemodialysing equipment adapted to filter the blood of a patient and said disposable or consumable components comprise a dialysis unit including a

filter which in use removes waste products from said patient's blood which is circulated by said haemodialysing equipment.

11. A chemical analyser comprising:

a reagent dispenser including a reagent vial,

identification means associated with said reagent vial,

sensing means associated with said chemical analyser, and

control means which inhibits the operation of said chemical analyser unless said sensing means detects said identification means.

12. A medical laser system for treating a patient comprising:

laser generating means,

optical means for conveying said laser from said laser generating means to said patient,

identification means associated with said optical means,

sensing means associated with said medical laser system,

control means which inhibits the operation of said medical laser system unless said sensing means detects said identification means.

13. An apparatus for preventing use of unauthorised disposable or cosumable components and allowing the use of authorised disposable or consumable components in conjunction with scientific apparatus as a chemical analyser substantially as herein described with reference to and illustrated by the accompanying drawings.

14. A chemical analyser substantially as herein described with reference to and illustrated by the accompanying drawings

15. A medical laser system substantially as herein described with reference to & illustrated by the accompanying drawings